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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,317	07/17/2003	Brian R. Micheli	DI-5829	3439

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EXAMINER	
DRODGE, JOSEPH W	

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/623,317	MICHELI, BRIAN R.	
	Examiner	Art Unit	
	Joseph W. Drodge	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-61 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-61 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 0104,0604.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1,5,8 and 28 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 24,25, 27 and 28 of copending Application No. 10/624,150 (same assignee, different inventive entity). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Instant claims 1,5,8 and 28 define the same combination of peritoneal dialysis components as claims 24,25,27 and 28, consisting of: catheter, fluid circuit, dialysate supply, cycler pump, cleaning device and discharge path/drain. The only differences are in descriptive phraseology not affecting relative scopes of the claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 1-61 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The instant specification of application 10/624,150 having inventors Childers, Pan and Lauman contains support for the identical

combinations of continuous peritoneal dialysis apparatus components and method steps, as in the instant claims. In addition to components discussed per the double patenting rejection, previously discussed, pages 19-20 of the Childers et al specification that discuss two separate sources/supplies of therapy fluid including dialysis fluid supply and osmotic agent solution supply, that form the basis of numerous of the instant claims.

Claims 1-12,15-21,24-26,28,29,32-37,40-45,48-55,57,58,and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Roberts et al Journal Publication "Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration" from Scholarly Review, ASAIO Journal 1999, pages 372-378. Roberts et al disclose the claimed peritoneal dialysis system including elements of dual lumen catheter (page 372, 1st column, and components shown in figure 3 that include closed loop fluid circuit, plural dialysate supplies, therapy fluid/osmotic agent or 'infusate' supply, cycler pumps, cleaning device at least including a sorbent cartridge and a discharge path/drain in the vicinity of the dialysate supplies. Also shown in figure 3 is a reservoir as required by independent claims 9,32,34,41 and 51. For independent claims 28,and 51, removal of urea is discussed on page 373, 1st column and in Table 1.

Regarding various dependent claims; two separate dialysate supplies totaling less than 4 or 6 liters are shown as well in figure 3, with osmotic agent supply inherently totaling less than 1.5 liters (see discussion on page 373, 2nd column, removal of urea by either non-selective sorbent or urease-urea removal specific media (page 374, 2nd column and page 376, 2nd column), presence of sorbent material (page 373, 2nd

column), maintaining of high urea and creatinine clearance levels (see Table 1 on page 376), the infusate constituting electrolytes and components with osmotic diffusive enhancing characteristics (page 376, see paragraph entitled "Wearable Regeneration Systems"), treatment periods of 8 hours or less (page 376, 2nd column, 3rd paragraph), continuous circulation and supply portions of 4 liters or less each (page 372, 1st column), and option of lower 3 liter or less amounts of osmotic solution utilized (see especially page 374 concerning treatment of relatively smaller canine systems).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 13,14,22,23,31,38,39,46,47,56 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Roberts et al Journal Article in view of Shockley et al patent 5,631,025.

Claims 13,14,22,23,38,39,46,47 and 56 differ in requiring that the osmotic agent fluid supply include dextrose. Shockley et al teach use of dextrose at column 5, lines

18-25 and supporting rationale. It would have been obvious to one of ordinary skill in the art to have included dextrose in the infusate supply of Roberts et al, as taught by Shockley, in order to enhance removal of various toxins by ultrafiltration from the recirculating dialysate.

Claims 31 and 60 differ in requiring substantial microglobulin clearance or removal rates. Schockley also teach removal of microglobulin at column 10, lines 13-18. It would have been further obvious to one of ordinary skill in the art to have employed a cleaning device with capability of removal of substantial amounts of the microglobulin of treated patients with the Roberts et al system, as suggested by Schockley et al, since microglobulin as a well known toxin accumulating in the peritoneal cavity requiring removal.

Claims 27,30,50 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Roberts et al Journal article in view of Ash patent 6,409,699. Claims 27,30,50 and 59 differ in requiring removal of phosphate or maintaining of substantial phosphate clearance rates. Ash teaches in column 15, lines 35-column 16, line 8 that phosphates are a toxin accumulating in the peritoneal cavity and can be removed by ultrafiltration of the dialysate. It would have also been obvious to have employed an ultrafilter in the circuit of Roberts et al to remove phosphates, as taught by Ash, in order to more completely clear the peritoneal cavity of toxin.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sakai patent 6,666,842 is of interest with respect to a continuous loop peritoneal dialysis system employing mainly ultrafiltration to regenerate the recirculating dialysate and remove toxins.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

October 1, 2005

JOSEPH DRODGE
PRIMARY EXAMINER